K1024404

510(k) Summary

DEC 8 2010

510(k) Applicant:	Ventus Medical, Inc. 1301 Shoreway Road, Suite 425 Belmont, CA 94002 (650) 632-4189 (phone) (650) 632-4198 (fax)
Contact:	Mike Nevares Director, Quality & Regulatory
Date Summary Prepared:	August 20, 2010
Name of Device:	PROVENT® Sleep Apnea Therapy: • PROVENT 80 (PROVENT HR) • PROVENT 50 (PROVENT SR)
Common Name:	Intraoral device
Classification Name:	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea (21 CFR 872.5570)
Product Code:	OHP
Predicate Devices:	Provent™ Professional Sleep Apnea Therapy, K071560 Provent™ Professional Sleep Apnea Therapy, K090398

Device Description

The PROVENT device is placed just inside the nostrils. The device directs expiratory flow through selected pathways, which increases intranasal pressure similar to the expiratory portion of the breathing cycle during CPAP use.

Indications for Use

For the treatment of obstructive sleep apnea (OSA).

Performance Data

Non-clinical and clinical testing demonstrated substantial equivalence of the modified devices to the predicate devices when used according to the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ventus Medical Incorporated
c/o Mr. Michael P. Nevares
Director, Quality and Regulatory
1301 Shoreway Road, Suite 425
Belmont, CA 94002

DEC 2 2010

Re: K102404
Trade/Device Name: PROVENT® Sleep Apnea Therapy
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices for Snoring, and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: OHP
Dated: August 27, 2010
Received: September 30, 2010

Dear Mr. Nevares:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: PROVENT® Sleep Apnea Therapy:

- PROVENT 80
- PROVENT 50

Indications for Use:

The PROVENT® Sleep Apnea Therapy Device is indicated for use in the treatment of obstructive sleep apnea (OSA).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices